UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,400	04/07/2006	Jouko Savolainen	LOYZ 20000SUS01	8987

27885 7590 03/30/2011

FAY SHARPE LLP
1228 Euclid Avenue, 5th Floor
The Halle Building
Cleveland, OH 44115

EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
03/30/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,400	SAVOLAINEN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,11,14-16,18-22,25,26,30 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,11,14-16,18-22,25,26,30 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/30/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 29, 2010 has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 3, 6-10, 12-13, 17, 23-24, 27-29, 31-32 are canceled. Claims 1-2, 4-5, 11, 14-16, 18-22, 25-26, 30, 33-35 are currently under examination.

Priority: The request for priority to FINLAND 20031506, filed October 15, 2003, and FINLAND 20031508, filed October 15, 2003, is acknowledged. A certified copy of FINLAND 20031508 has been filed in this case on April 7, 2006, and is in the English language and a certified copy of FINLAND 20031506 has been filed in this case on April 7, 2006, and is in a non-English language.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-5, 20-22, 26, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krochta et al. (US 5543164; previously cited) in view of Savolainen (US 6797810; previously cited).

Krochta et al. disclose a method for preparing a protein-based film comprising (i) treating an aqueous solution of protein to effect disulfide formation in order to form a denatured protein solution; and (ii) applying said denatured protein solution to a food item and drying to form a coating for the food item (col. 13 lines 10-19). Krochta et al. also disclose that said method can further comprise a step of adding a food grade plasticizer to said denatured food protein solution (col. 13 lines 39-42). Krochta et al. disclose that the thiol-disulfide exchange can be effected by chemical treatment, i.e. include chemical treatment by sulfites (col. 5 lines 24-43). Krochta et al. do not explicitly teach a chemical treatment step with a sulfite.

Savolainen discloses a sulfitolysis chemical treatment step that effects disulfide formation of proteins, i.e. whey and soy proteins (col. 5 lines 15-21). Savolainen discloses a method comprising a) providing a whey protein solution, b) contacting said whey protein solution with sulfite ions (i.e. sodium sulfite), and c) adjusting the pH of said solution to a pH below 7 (col. 7 lines 5-25, col. 9, col. 10-11 example 1, 4, col. 13-14). Savolainen discloses that that the sulfitolysis process creates sufficient cleavage of disulfide bonds and therefore renders oxidization unnecessary and speeds up the thiol-disulfide exchange reaction by making it economically more profitable (col. 5 lines 22-29).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Krochta et al. by substituting the sulfitolysis treatment step

of Savolainen for the chemical treatment step disclosed in Krochta et al. for a method of preparing a protein-based film (claims 1-2, 4-5, 20-22, 26, 35). The motivation to do so is given by Savolainen, which disclose that the sulfitolysis chemical treatment step to effect disulfide formation in a protein solution omits oxidation and therefore simplifies and speeds up the thiol-disulfide exchange process.

Regarding the limitation of claim 1, i.e. having about 2 to about 4 free sulfhydryl groups per protein, this limitation is believed to be within the scope of Krochta et al. in view of Savolainen since said references disclose the instant steps of preparing a protein-based film. Further, see column 7 lines 4-15, where Savolainen discloses that the number of free sulfhydryl groups present can be made use as functional properties, i.e. gelation, hydrolyzability/digestibility and that under acidic conditions, i.e. pH 1.5-4.5, the sulfitolysis process liberates such that from the cleaved disulfide group two sulfhydryl groups remain.

In their remarks, Applicants assert that (1) Applicants submit that not all claim limitations are met. In particular, it appears clear to Applicants that both Krochta '164 and Savolainen contemplate that all of their proteins undergo denaturing, or in other words that in their solutions, all proteins are modified and have free sulfhydryl groups which can undergo reaction. The present claims require both modified proteins with sulfhydryl groups and unmodified proteins. Thus, the present claims are different from the combination of references in this manner. (2) In addition, please note that claim 1 requires the completed protein network to still have free sulfhydryl groups. In contrast, Krochta '164 discusses oxidizing any free thiol groups in column

5, lines 44-53. Savolainen also discusses oxidizing free sulfhydryl groups at column 7, lines 24-38. These two disclosures in the cited references appear to teach away from present claim 1. Claim 20 similarly recites modified proteins having free sulfhydryl groups. Thus, even if the asserted combination were tenable, which Applicant disputes, the combination does not teach or disclose the claimed subject matter.

Applicant's arguments have been fully considered but they are not persuasive.

(1) Response: It should be noted that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). However, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). MPEP 2141.02.

In this instance, Savolainen discloses that the sulfitolysis process creates sufficient cleavage of disulfide bonds and therefore renders oxidization unnecessary and speeds up the thiol-disulfide exchange reaction by making it economically more profitable (col. 5 lines 22-29). Savolainen further discloses that the sulfitolysis process is performed without using an oxidizing agent (abstract) and that there are free sulfhydryl groups created in the protein (col. 14 lines 12-18). Savolainen further discloses that the number of free sulfhydryl groups present can be made use as functional properties, i.e. gelation, hydrolyzability/digestibility (col. 7 lines 8-15). Further, under acidic conditions, i.e. pH 1.5-4.5, the sulfitolysis process liberates such that from the cleaved disulfide group two sulfhydryl groups remain (col. 7 lines 4-7). Therefore, it would

be reasonable for one of ordinary skill to optimize the conditions at which the sulfitolysis process should be performed at in order to determine the optimal number of free sulfhydryl groups that should be present per protein in a protein-based film since it was known in the art at the time that free sulfhydryl groups correlate with the functional properties of a protein-based film.

(2) Response: Savolainen does not just discuss oxidizing free sulfhydryl groups. As noted in the response of (1), Savolainen also discloses performing the sulfitolysis process without using an oxidizing agent (abstract) and that there are free sulfhydryl groups created in the protein (col. 14 lines 12-18).

For at least these reasons, the 103(a) rejection is maintained.

Claims 11, 14-16, 18-19, 30, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krochta et al. (US 5543164; previously cited) in view of Savolainen (US 6797810; previously cited). The teachings of Krochta et al. in view of Savolainen are outlined above. Krochta et al. also disclose that a protein-based film made from whey proteins can be formed on a food item (col. 5 lines 55-60), and can be formed around a lipid (col. 6 lines 7-10). The protein-based film can be formed without heat treatment (col. 5 line 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the whey protein film of Krochta et al. in view of Savolainen on a food item, edible product, and/or any other type of appropriate product as suggested by Krochta et al. because Krochta et al. suggest that an edible protein-based coating can be used to coat foodstuff to make it more appealing or to protect it from moisture (claims 11, 14-16, 18-19, 30, 33-34).

Response: The reasons for maintaining the Krochta et al. and Savolainen references are the same as noted above.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krochta et al. (US 5543164; previously cited) in view of Savolainen (US 6797810; previously cited). The teachings of Krochta et al. in view of Savolainen are outlined above. Savolainen discloses the sulfite amount is 0.02-0.2 M (col. 7 lines 55-57). Savolainen does not explicitly teach the amount of sulfite used is 0.01-0.06% (w/v).

However, it would have been obvious to one of ordinary skill in the art to modify the amount of sulfite used in order to obtain proteins with various degrees of modification that will result in said proteins having the appropriate functional properties (col. 7 lines 5-25; claim 25). Also, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.").

Response: The reasons for maintaining the Krochta et al. and Savolainen references are the same as noted above.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marsha M. Tsay/
Primary Examiner, Art Unit 1656

March 23, 2011